Proposed Remarks:

Claims 1-18 were originally presented in this application. Claims 2 and 15 were previously canceled, and claims 6-14 and 16-18 have been withdrawn as being drawn to non-elected embodiments. Thus, claims 1 and 3-5 remain pending for examination on the merits. Claim 1 is in independent form.

In the Pre-Interview Office Action mailed March 12, 2010 ("Office Action"), the Examiner rejects independent claim 1 under 35 U.S.C. § 102(b) as being anticipated by PCT Published Application No. WO 99/20745 to Kim et al. ("Kim"). Alternatively, the Examiner rejects independent claim 1 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,360,614 to Fox et al. ("Fox"). In another alternative, the Examiner rejects independent claim 1 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,962,416 to Katzen et al. ("Katzen").

In response to these rejections, Applicants propose amending independent claim 1 to include the limitations "wherein said coating composition is substantially insoluble in the rumen of an animal" and "wherein said coating composition solubilizes in an environment having a pH in the range of from 1.5 to 2, thereby rendering said at least one comestible particulate material available for digestion." Support for these proposed amendments can be found, for example, in the specification at page 3, lines 14-16, and page 6, lines 14 and 15, respectively.

Referring initially to the rejection of independent claim 1 over Kim, Applicants submit that Kim fails to disclose the proposed limitation whereby the coating composition solubilizes in an environment having a pH in the range of from 1.5 to 2, either expressly or inherently. This is at least because the teachings of Kim are directed to coating a granule containing lactic acid bacteria in a manner that allows the lactic acid bacteria to survive the environment of a human stomach and thereby proceed intact to the lower gastrointestinal region. For instance, Kim states that "[i]n the present invention, since the coated granule contains active lactic acid bacteria in a high ratio and is very sensitive to acidity, the bacteria contained therein can survive under human gastric circumstance and the granule then can be disintegrated rapidly in the intestine" (Kim, page 3, lines 24-28).

The human stomach generally has a very low pH. For example, Kim notes that gastric juice, found in the stomach of humans, has a pH of about 2. Specifically, Kim states that "since lactic acid bacteria are very unstable under pH of 4, almost all the ingested lactic acid bacteria are destructed

at the acidity of gastric juice (about pH 2)" (Kim, page 1, lines 26-28). Thus, because the goal of Kim is to protect the lactic acid bacteria in low-pH environments, the coating composition employed by Kim is specifically designed to not be soluble at low pH (such as a pH of 2). Further evidence of Kim's failure to teach the proposed amendment can be found in Table 2 of Kim, which tests for disintegration of the coatings prepared in Kim's Examples 1-9. As can be seen in Table 2 of Kim, none of the samples prepared had any change after being subjected to artificial gastric juice having a pH of 1.2, but all disintegrated under 3 hours in a pH of 6.8. Thus, Applicants submit that the coating compositions employed by Kim do not solubilize in an environment having a pH in the range of from 1.5 to 2. Accordingly, Kim fails to either expressly or inherently disclose this proposed limitation to independent claim 1. Therefore, Kim would not anticipate independent claim 1, if amended in the manner proposed.

With respect to Fox, Applicants submit that Fox similarly fails to teach a coating composition having the proposed limitation of being able to solubilize in an environment having a pH in the range of from 1.5 to 2, thereby rendering the comestible particulate material available for digestion. First, nowhere does Fox ever mention that its coating composition has such a property. Thus, Fox fails to expressly disclose the proposed limitation to independent claim 1. Additionally, as is discussed in greater detail below, Applicants submit that Fox fails to inherently disclose this limitation.

The stated purpose of Fox is to provide a "delayed release encapsulated carbohydrate composition" (Fox, column 1, lines 8-9). This is accomplished by encapsulating the carbohydrate in a coating that "causes a timed delay release of the carbohydrates in the digestive tract of the human body" (Fox, column 1, lines 58-60). Thus, the coating employed by Fox limits the solubility of the particulate in the digestive tract, such that carbohydrates are slowly released. In contrast, the proposed amendment requires the coating composition to solubilize at a pH of from 1.5 to 2, thereby rendering the core comestible composition available for digestion.

Although not stated by Fox, one skilled in the art would reasonably conclude that the coating employed by Fox would remain largely intact in the stomach of a human (i.e., at a pH of from 1 to 3). This is because it is known that metabolism of carbohydrates by humans is achieved primarily in the duodenum, immediately downstream of the stomach in a human gastrointestinal tract. As known in the art, breakdown of carbohydrates does not occur in the stomach due to the highly acidic

environment. If the time-released coating were dissolved in the stomach, it is reasonable to conclude that the primary metabolism of the carbohydrate in the duodenum would not be delayed, since the carbohydrate would no longer be protected. Additionally, the duodenum is maintained at a higher pH than the stomach due to bile secreted by the liver into the duodenum. This fact could reasonably explain why Fox tested its coating materials at pH levels higher than those typically found in a human stomach. For instance, Examples 1-5 of Fox tested delayed release times in water (which generally has a pH of about 7), and the sample prepared in Example 6 was tested in a buffer having a pH of 4.5. This evidence further supports the conclusion that Fox intended its coating material to survive the low pH environment of the stomach to be broken down in the higher pH environment of the duodenum. Accordingly, Applicants submit that Fox neither expressly nor inherently discloses a coating composition that "solubilizes in an environment having a pH in the range of from 1.5 to 2, thereby rendering said at least one comestible particulate material available for digestion."

Furthermore, as noted above, Applicants have proposed amending independent claim 1 to additionally include the limitation "wherein said coating composition is substantially insoluble in the rumen of an animal." As the present specification notes, the rumen of an animal has a pH that is generally greater than about 5. Nowhere does Fox disclose this limitation. In fact, as noted above, all but one of Fox's Examples tested for delayed release times were performed in an environment having a pH greater than about 5 (i.e., water). In each of Fox's Examples 1-5, the coating eventually dissolved in water and released the carbohydrate core. Therefore, Fox fails to disclose either of the above proposed limitations, and thus would not anticipate independent claim 1 if amended in the proposed manner.

Finally, regarding Katzen, Applicants submit that this reference fails to disclose all elements of independent claim 1 either as currently written or if amended in the proposed manner. First, nowhere does Katzen disclose the proposed limitation reciting "wherein said coating composition solubilizes in an environment having a pH in the range of from 1.5 to 2, thereby rendering said at least one comestible particulate material available for digestion." Furthermore, as discussed in greater detail below, nowhere does Katzen disclose the limitation of independent claim 1 reciting "wherein said protein source is selected from the group consisting of vital wheat gluten, wheat protein isolate, wheat protein derivatives, soy protein, and mixtures thereof."

In the Office Action, it appears to be the Examiner's position that Katzen's disclosure of a "wheat gluten flour" qualifies as one of the listed protein sources in independent claim 1, particularly the recited "vital wheat gluten." However, Applicants submit that, as would be recognized by one skilled in the art, wheat gluten flour is not the same thing as vital wheat gluten. According to the website www.wheatfoods.org, wheat gluten flour is a "processed form of high protein wheat containing much higher protein that bread flour, is used by bakers in combination with low protein or non-wheat flours. The gluten flour improves baking quality and produces yeast breads of high protein content" (http://www.wheatfoods.org/aboutwheat-wheat-flours/index.htm; see attached Exhibit 1). In contrast, vital wheat gluten is "derived from wheat flour and is the texture of flour; it is concentrated dried gluten protein with very little starch remaining" (*Id.*). Thus, the difference between the two is that wheat gluten flour has a higher starch content than vital wheat gluten.

In contrast to the protein sources listed in independent claim 1, the flour employed by Katzen needs to have a minimum amount of starch present. This is because starch allows Katzen's coating composition to gelatinize or polymerize under high temperature and pressure, which is a critical feature of Katzen's invention (*see* Katzen, Abstract). Thus, Applicants submit that none of the flours employed by Katzen disclose the recited vital wheat gluten, wheat protein isolate, wheat protein derivatives, or soy protein.

Furthermore, as noted above, Applicants have proposed amending independent claim 1 to additionally include the limitation "wherein said coating composition is substantially insoluble in the rumen of an animal." Nowhere does Katzen disclose this limitation. In fact, Katzen notes that digestion of its composition "beings in the mouth by action of salivary amylase (ptyalin) with an optimum pH of 5.5 to 6.5." Thus, because Katzen indicates that digestion of its coating composition begins in an environment having a pH of 5.5 to 6.5, Katzen does not disclose, either expressly or inherently, the proposed limitation of "wherein said coating composition is substantially insoluble in the rumen of an animal." Accordingly, Applicants submit that Katzen fails to disclose all elements of independent claim 1, either as currently written or if amended in the manner proposed above, and therefore does not anticipate independent claim 1.

In view of the foregoing, Applicants submit that independent claim 1, if amended in the proposed manner, is not anticipated by the art of record, and thus would be in condition for

allowance. Furthermore, although dependent claims 3-5, which depend from independent claim 1, all recite additional patentable features, these claims should also be in condition for allowance given their dependence on an allowable base claim.

Any fee which might be due in connection with this application should be applied against our Deposit Account No. 19-0522.

Respectfully submitted,

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ATTORNEYS FOR APPLICANTS

Wheat Flours

All-Purpose Flour
All-purpose flour is the finely ground endosperm of the wheat kernel separated from the bran and germ during the milling process. All-purpose flour is made from hard wheats or a combination of soft and hard wheats from which the home baker can make a complete range of acceptable backed products --- yeast breads, cakes, cookies and pastries.

- Enriched all-purpose flour has iron and 4 major B-vitamins (thiamin, niacin, riboflavin and folic acid) added in amounts equal to or exceeding that in whole wheat flour. Actually, all enriched flour has twice the folic acid as does whole wheat flour. All but about 5 percent of white flour in the United States is enriched.
- Bleached all-purpose flour is exposed to chlorine gas or benzoyl peroxide to whiten and brighten flour color. Chlorine also affects baking quality by "maturing" or oxidizing the flour, which is beneficial for cake and cookie baking. The bleaching agents react and do not leave harmful residues or destroy nutrients.
- Unbleached all-purpose flour is bleached by oxygen in the air during an aging process and is off-white in color. Nutritionally, bleached and unbleached flours are equivalent. But bleached flour is beneficial for cake and cookie baking.

Bread Flour
Bread flour, ground from the endosperm of the hard red spring wheat kernel, is milled primarily for commercial bakers, but is available bleached or unbleached at most grocery stores. It is usually enriched. Although similar to all-purpose flour, it has greater gluten strength and is generally used for yeast breads.

Self-Rising Flour
Self-rising flour is an all-purpose flour with salt and leavening added. One cup of self-rising flour contains 1 1/2 teaspoons baking powder and 1/2 teaspoon of salt. Self-rising can be substituted for all-purpose flour in a recipe by reducing salt and baking powder according to these proportions.

Cake Flour
Cake flour, milled from soft wheat, is especially suitable for cakes, cookies, crackers and pastries. it is low in protein and low in gluten.

Pastry Flour
Pastry flour has comparable protein, but less starch than cake flour. It is milled from a soft, low gluten wheat and is used for pastries.

Gluten Flour
Gluten flour, processed from high protein wheat and containing much higher protein than bread flour, is used by bakers in combination with low protein or non-wheat flours. The gluten flour improves baking quality and produces yeast breads of high protein content.

Vital Wheat Gluten
Vital wheat gluten is derived from wheat flour and is the texture of flour; it is concentrated dried gluten protein with very little starch remaining.

Semolina
Semolina is the coarsely ground endosperm of durum wheat. high in protein, it is used by American and Italian manufacturers to make high quality pasta products such as macaroni and spaghetti. It is also used for couscous in Africa and Latin America.

Durum Flour
Durum flour is a by-product in the production of semolina and is used for American noodles, some types of pasta and occasionally in specialty breads.

Whole Wheat Flour
Whole wheat flour is a coarse-textured flour containing the bran, germ and endosperm. The presence of bran reduces the gluten development, therefore, bake products make from whole wheat flour tend to be heavier and denser than those made from white flour.

Whole wheat flour is rich in B-vitamins, vitamin E and protein, and contains more trace minerals and dietary fiber than white flour. It also contains about five percent fat. In most recipes, whole wheat flour can be mixed half and half with white flour. Graham flour is another term for whole wheat flour.

Farina
Farina is the coarsely ground endosperm of hard wheats. It is the prime ingredient in many hot breakfast cereals. it can also be used for pasta.

Download this Resource:

Grains of Truth about Wheat Flour

More Information:

- What is Wheat?
- List of wheat foods
- Wheat Kernels
- White Wheat
- Wheat Facts

EXHIBIT
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